510(K) SUMMARY

K101641

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

JUN 16 2011

1. Submitter's Name: **AG Digital Technology Corp.**

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Contact: Mr. Telvin Ju / Genral Manager

2. Device Name :

Trade Name: **AG Thermographic Camera, Model no.: ATIR-M301**

Common Name: Telethermographic system

Classification name Telethermographic system (adjunctive use)

3. DEVICE CLASS The **AG Thermographic Camera (Model no.: ATIR-M301)** has been classified as

Regulatory Class: I

Product Code: LHQ

Regulation Number: 21 CFR 884.2980

4. Predicate Device: The predicate device is the

- **TELETHERMOGRAPHIC CAMERA ,** Model No. SERIES A, E, S AND P (K033967) marketed by **FLIR SYSTEMS**
- **TELESIS DIGITAL INFRARED THERMAL IMAGE SYSTEM** , Model No. **SPECTRUM 9000MB** (K020783) marketed by **TELESIS TECHNOLOGIES INC.**

Intended Use: The **AG Thermographic Camera (Model no.: ATIR**

M301) is intended to use as an adjunct to other clinical diagnostic procedures by quantifying differences in skin surface temperature changes. It can visualize and digitalize body surface temperature distribution and temperature changes. The device is intended for use by qualified healthcare personnel trained in its use.

6. Device Description: The **AG Thermographic Camera (Model no.: ATIR-M301)** consists of an infrared camera, accessories, and PC visualization/analysis software. It is a non-contact, non-invasive, and non-radiating infrared system capable of imaging and storing thermal patterns generated by the human body. It employs passive infrared emission sensing technology to capture the thermal data and uses proprietary software to display the temperature distribution pattern as an image. **It is suitable for imaging adult human targets and can be used in hospitals,** acute and sub-acute healthcare settings, nursing homes, clinics, homes, public areas such as airports, and any environment where healthcare is provided by a healthcare professional.

7. Comparison to 510(k) Predicate Devices The **AG Thermographic Camera (Model no.: ATIR-M301)** have the same intended use, principles of operation, and similar technological characteristics as predicate devices. Please find Technological Characteristics as follows

Item	AG Digital ATIR-M301	FLIR A20M	TELESIS SPECTRUM 9000MB
Technology	FPA uncooled Mircrobolometer	FPA uncooled Mircrobolometer	FPA uncooled Mircrobolometer
Material	Amorphous Silicon	Amorphous Silicon	VOx

Spectral Response	8 ~ 14um	7.5 ~ 13 um	7 ~ 14 um
Array Resolution	320x240	160x120	320x240
Thermal Sensitivity	< 0.1 °C	0.09~0.12°C	0.07°C
Optics	50mm F=0.7 FOV= 18.1°(H) ×13.7°(V)	F=1.2 FOV= 24°(H) ×18°(V)	50mm F=0.83 FOV= 18.7°(H)×14°(V)
Focus	Electric motor driving 0.5M -∞	Manual, 0.3M - ∞	Manual, 0.6M - ∞
Spatial Resolution	≦ 1 mrad	2.7mrad	1 mrad
Temperature Range	30℃~40℃	-20~+250 °C (-4~+482 °F)	10°C to 40°C
Temperature Resolution	0.1℃	0.1℃	0.1℃
Accuracy	< ±1℃	± 2 °C or ± 2 % of reading	-
Refresh Rate	30 Frames/sec	60 Frames/sec	60 Frames/sec
Working temperature	20 - 26℃	-15℃~50℃	18℃~28℃
Operating Temperature	24°C ± 2°C	-15℃~50℃	20-22.2℃
Data Output	USB2.0	RS-232, IEEE-1394, TCP/IP	RS-170
Data processing	personal computer	Camera and personal compute	personal compute
Display	GUI on PC	GUI on PC	GUI on PC
User interface	Software on PC	Software on PC	Software on PC
Power Supply	AC adapter 110/240VAC,50/60Hz	AC adapter 110/220VAC,50/60Hz	115~230 VAC 50~60 Hz
Weight	1.3 Kgs	1.7 LB	3 LB

8. Substantial Equivalence Discussion

AG Thermographic Camera (Model no.: ATIR-M301) has the same general design with the predicate devices

Since the Applicant has selected Legally Marketed Devices

- **TELETHERMOGRAPHIC CAMERA** , Model No. **SERIES A, E, S AND P** (K033967) marketed by **FLIR SYSTEMS**
- **TELESIS DIGITAL INFRARED THERMAL IMAGE SYSTEM** , Model No. **SPECTRUM 9000MB** (K020783) marketed by **TELESIS TECHNOLOGIES INC.**

The has the following similarities to the predicate devices in:

- having the same intended use.
- using similar operating principle,.
- using similar technological characteristics

In summary, the **AG Thermographic Camera (Model no.: ATIR-M301)** described in this submission are, in our opinion, substantially equivalent to the predicate devices.

9. Performance Data

AG Thermographic Camera (Model no.: ATIR-M301) meets EN 60601-1 (IEC 60601-1), EN 60601-1-2 (IEC 60601-1-2), and Performance tests including

- Temperature accuracy
- Environment temperature factor test
- Focus test
- Distanced object temperature test
- Thermal image handling
- Small area temperature statistics and two-area comparison
- Patient history record handling

10. Safety and Effectiveness

The **AG Thermographic Camera (Model no.: ATIR-M301)** meet electrical Safety standard such as EN 60601-1 (IEC 60601-1), EN 60601-1-2 (IEC 60601-1-2). so it is safe for human body. Additionally,

Performance tests including

- Temperature accuracy
- Environment temperature factor test
- Focus test
- Distanced object temperature test
- Thermal image handling
- Small area temperature statistics and two-area comparison
- Patient history record handling

were conducted to ensure the device can work as the intended performance.

Therefore, the device is of safety and effectiveness.

Conclusion

AG Thermographic Camera (Model no.: ATIR-M301) have the same intended use, principles of operation, and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **AG Thermographic Camera (Model no.: ATIR-M301)** are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AG Digital Technology Corp.
% Ms. Jennifer Reich
Senior Consultant
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JUN 16 2011

Re: K101641
Trade/Device Name: AG Thermographic Cmaera, Model no: ATIR-M301
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: LHQ
Dated: January 26, 2011
Received: January 7, 2011

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101641

Device Name: **AG Thermographic Camera,**
Model no.: ATIR-M301
AG Digital Technology Corp.

Indications For Use:

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Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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